



Promoting Appropriate Prescribing: How Education and Cooperation of Physicians and Pharmacists Can Address the Problems of Inappropriate Prescribing and Dispensing

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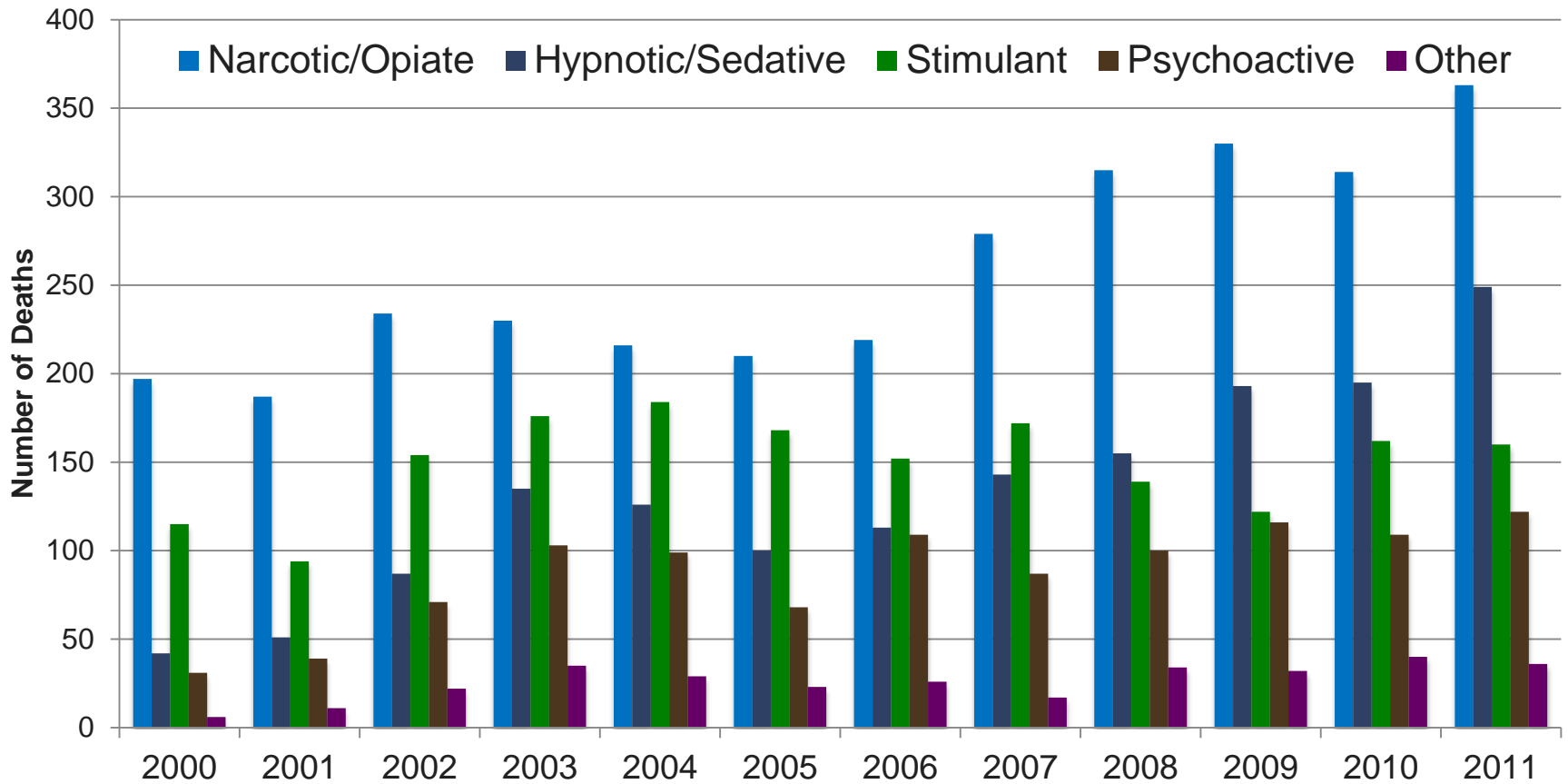
UC San Diego
HEALTH SYSTEM

DEA aims big in Cardinal Health painkiller case.

Prescription painkillers and other evidence from a CVS store Feb. 4 in Sanford, Fla. (Florida Today, Feb. 28, 2012)



Unintentional Deaths Due To Prescription Medications, 2000 - 2011



Clinician's Dilemma:

Combating Pain/Defending Against Rx Drug Abuse

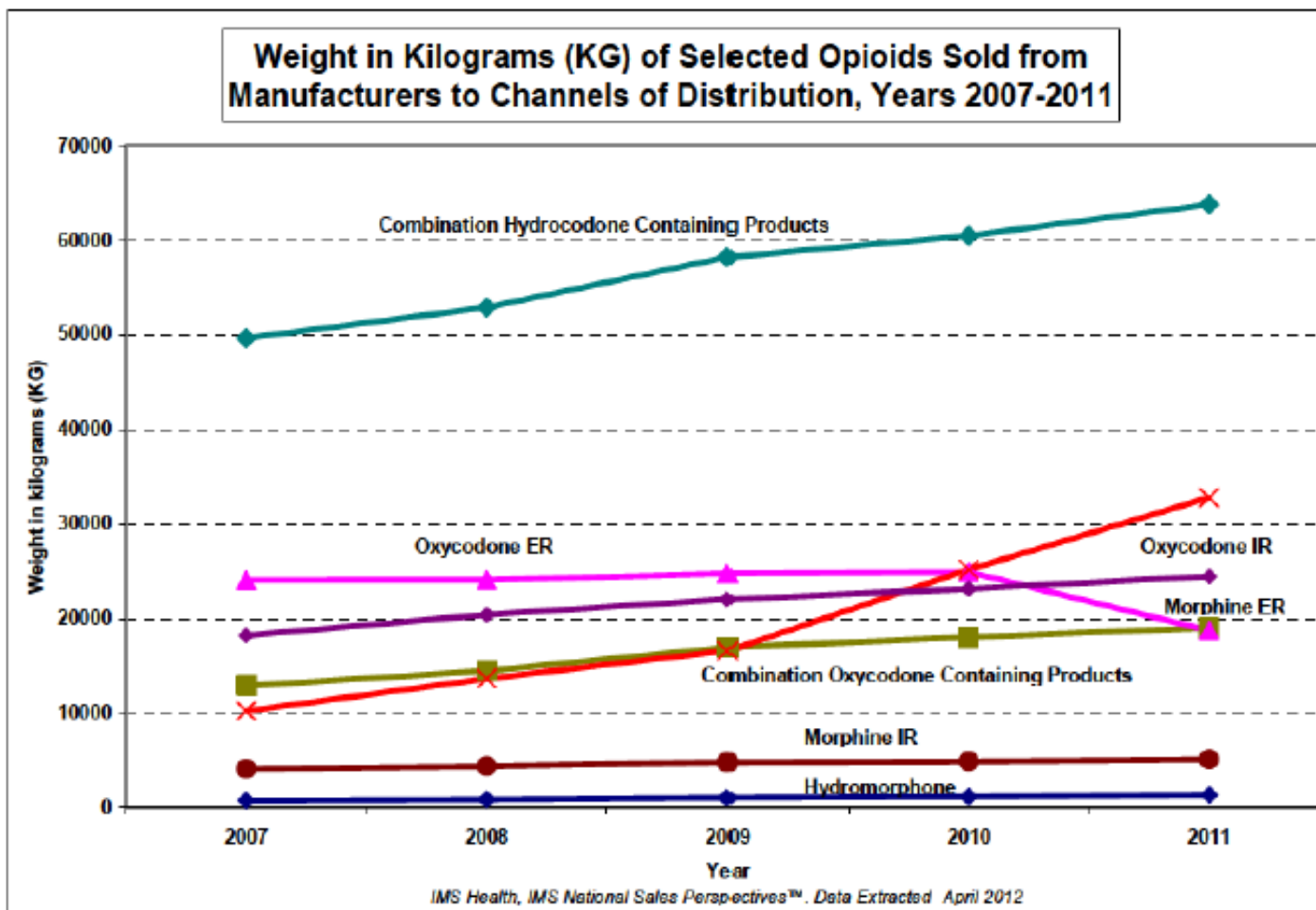
Healthcare Professionals

- Lack of knowledge of medical standards, current research, clinical practice guidelines.
- Inadequate knowledge about addiction, dependence and misuse
- Perception of regulatory scrutiny.
- Understanding of regulatory policies and processes.
- Poor assessment and documentation
 - Types of pain
 - Abuse potential/patient history of abuse
 - Lack of documentation

Uniform Controlled Substances (CS) Act (1970)

Schedule I--High potential for abuse, no current, acceptable medical use in U.S., lack of safety	<u>Select examples:</u> Heroin, Peyote, LSD
Schedule II--High abuse potential, medical use, severe restriction, may lead to psychological or physical dependence	Anabolic steroids fentanyl, morphine, oxycodone, metha- done
Schedule III--Less abuse potential than above, medical use, moderate or low possibility of physical dependence or high psychological dependence	Anabolic steroids, GHB, opioid combos. (i.e., Vico- din®, Tussionex®) buprenorphine
Schedule IV--Lower abuse potential, medical use, limited psych. or physical dependence	Diazepam, zolpidem lorazepam, Soma®
Schedule V--Low abuse potential, medical use, limited psych. or physical dependence	Cough med w/ cod.

2012 FDA Briefing Document: Drug Safety and Risk Management Meeting (DSaRM) IMS Health: 4/2012



Call to Action:

- Prescription drug abuse has surpassed the abuse of cocaine and heroin combined
- Pharmacists may not repeatedly ignore red flags and fill prescriptions because they come from a licensed prescriber
- **Criminal and administrative actions**
 - DEA has increased actions against pharmacies and licensees
 - Pharmacist's Corresponding Responsibility.
- In light of red flags the pharmacist should exercise additional diligence and improved documentation before filling the prescription.

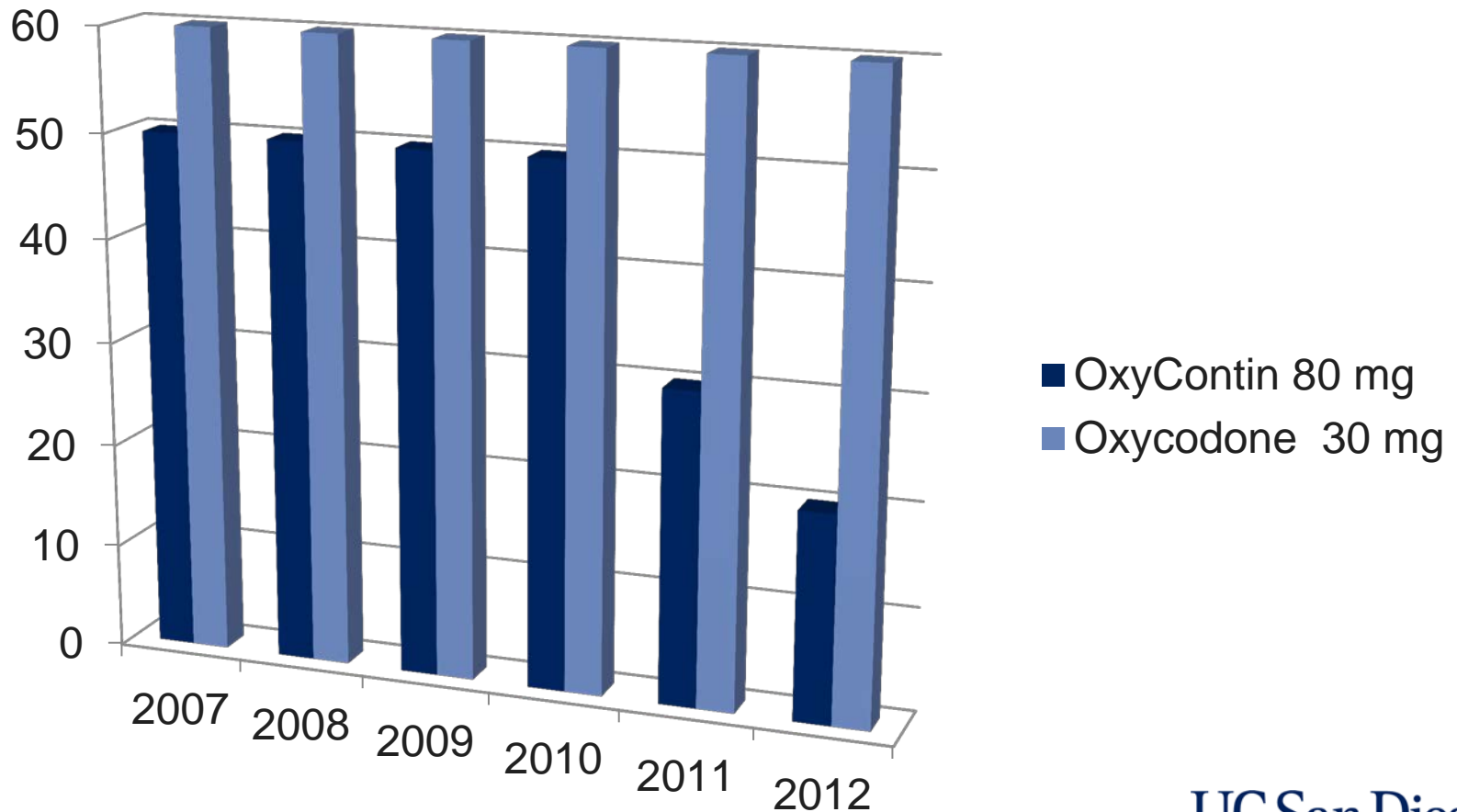
Deaths related to selected meds. (SD Coroner, 2012)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Alprazolam		5	1	7	6	15	13	13	15	23	28	52
Diphenhydramine	2	5	14	13	14	10	14	21	17	21	21	30
Hydrocodone	10	14	23	23	26	21	32	28	34	44	37	52
Methadone	7	10	18	20	29	32	35	43	47	41	53	53
Oxycodone	8	17	21	16	16	19	17	45	52	43	48	65

Reformulated OxyContin® Released August 10, 2010

- **Oxycodone 30 mg replaces OxyContin 80 mg**
- Maximum allowed by most Medicare Part D Plans (7200 mg per month per beneficiary)
- First 11 months after reformulation, abuse of OxyContin® declined by 49%

Average Street Price Per mg OxyContin® vs Oxycodone 2006-2012 (L.A. HALT)



Federal Law: **Corresponding Responsibility**

21 CFR 1306.04 Purpose of Issue of Prescription

- (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests with the pharmacist** who fills the prescription. ...

Federal Law: Corresponding Responsibility

21 CFR 1306.04 Purpose of Issue of Prescription

- (a) . . . An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Corresponding Responsibility of the Pharmacist for Legitimacy of Rx

- A controlled substance shall only be issued for a legitimate medical purpose.
- Following are not legal prescriptions:
 1. Order not in the usual course of professional treatment.
 2. Order for an addict or habitual user of controlled substances not in the course of professional treatment or as part of a narcotic treatment program.

What Would you Do? “New Patient”

Rx from an MD in Los Angeles

- “Pain Specialist”, D.O

Patient lives in South East San Diego.

DoB: 6/23/85

Three Rxs on one written prescription:

- 1) Oxycontin 80 mg TID
- 2) Xanax 2 mg TID
- 3) Soma 350 mg TID

Red Flags: Possible Drug Diversion

- Physician practice location
- Patient home/work location
- Practitioner issued inordinately large quantity of CS prescriptions.
- Patient uses different pharmacies to avoid detection
- Age of the patients (between 20-40)
- Nonspecific diagnosis i.e., back pain
- Issued multiple prescriptions
- Prescribing drug “cocktails” (include oxycodone, hydrocodone, alprazolam, carisoprodol)
- No individualization of dosing
- Multiple prescriptions for the strongest dosages of hydrocodone and alprazolam
- “Early” refills
- Patients paying cash.
- Parking lot activity?

Corresponding Responsibility of Pharmacist for Legitimacy of Prescription

- A pharmacist has the legal right to refuse to dispense a controlled substance when he/she believes it is not issued in good faith.
- Pharmacist has the right and duty to ascertain from the prescriber the purpose for issuing the prescription when in doubt as to its legitimate purpose.

Controlled Substances Law: Doctor Shopping

11154. Prescription, etc. Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.

(a) Except in the regular practice of his or her profession, no person shall knowingly **prescribe, administer, dispense**, or furnish a controlled substance to or for any person or animal **which is not under his or her treatment** for a pathology or condition other than addiction to a controlled substance, except as provided in this division.

(b) No person shall knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance.

Guidelines for Prescribing

(Adapted from the Medical Board of California, rev. 2007)

1. History/Physical Examination

Include assessment of pain, physical and psychological function, substance abuse history, coexisting diseases recognized medical indication.

2. Treatment plan, Objectives

Objectives for tx. success (pain relief, improved physical or psychosocial function) indicate further diagnostic evals., other txs. planned. If a clinical decision is made to withhold opioid medications, document basis for the decision.

Guidelines for Prescribing

(Adapted from the Medical Board of California, rev. 2007)

3. Informed consent

- Discuss the risk and benefits of the use of controlled substances and other treatment modalities.
- Written consent agreement for chronic pain.

4. Periodic review

Review the course of the tx. and any new information about etiology or changes in the pain of patient's state of health.

- Pts. on CS should be seen regularly as required by standard of care.
- Response to treatment

Guidelines for Prescribing

(Adapted from the Medical Board of California, rev. 2007)

5. Consultation

Consider referral of the patient as necessary for additional evaluation and treatment. Complex pain problems may require a pain specialist.

- Coordination of care in prescribing chronic opioids
- Dual diagnosis treatment complies with B&P 2241 and 2241.5.

6. Records

Accurate and complete records of evaluation, consultations, treatment plan objectives, informed consent treatments, medication agreements, periodic reviews. Pain levels, quality of life documentation.

- Document periodic reviews at least annually

Guidelines for Prescribing

(Adapted from the Medical Board of California, rev. 2007)

7. Compliance with Controlled Substances Laws and Regulations

Prescriber must be appropriately licensed, have a valid controlled substances registration and comply with federal and state laws and regulations.

Refer to DEA Manual for Practitioners (physicians and surgeons) and Pharmacist's Manual

- No minimum or maximum number of medications
- Supervision of PAs and NPs should carefully review respective supervision requirements.

Education and Accountability for Opioid/CS use

- Set standards (acute vs. evaluate chronic use)
- Provide guidance (ED, Pain Education/training, Med. Error Review)
- Review for competency (Quality Assurance Process Improvement/Performance Improvement)
- Accountability (Pain Task force, Safe Medication Practice (MERP in California))
- Update policies and procedure
- Evaluate CURES data and disseminate summary reports for review?

CURES: CA Dept. of Justice/Bureau of Narcotic Enforcement/PDMP

Prescription Drug Monitoring Program

CURES / PDMP

Controlled Substance Utilization Review and Evaluation System (CURES), California Prescription Drug Monitoring Program (PDMP)

The California Department of Justice, has a Prescription Drug Monitoring Program (PDMP) system which allows pre-registered users including licensed healthcare prescribers eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards to access timely patient controlled substance history information.

The California Attorney General's Office said that if doctors and pharmacies have access to controlled substance history information at the point of care it will help them make better prescribing decisions and cut down on prescription drug abuse in California. The role of the PDMP entrusts that well informed prescribers and pharmacists can and will use their professional expertise to evaluate their patients care and assist those patients who may be abusing controlled substances.